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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,920	01/29/2002	Michael A. Adams	PTQ-0040	4865

7590

01/26/2004

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Marlton, NJ 08053

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,920

Applicant(s)

ADAMS ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-89 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 51-89 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1642

DETAILED ACTION

Re: Adams *et al.*

Claims 51-89 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring RTP/DRG1 and PAI-1, classified in class 435, subclasses 6, 7.1.
2. Claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring RTP/DRG1 and uPAR, classified in class 435, subclasses 6, 7.1.
3. Claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring PAI-1 and uPAR, classified in class 435, subclasses 6, 7.1.
4. Claims 51-63, as specifically drawn to a method for diagnosing hypoxia in an individual comprising measuring RTP/DRG1, PAI-1, and uPAR classified in class 435, subclasses 6, 7.1.

5. Claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring RTP/DRG1 and PAI-1, classified in class 435, subclasses 6, 7.1.
6. Claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring RTP/DRG1 and uPAR, classified in class 435, subclasses 6, 7.1.
7. Claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring PAI-1 and uPAR, classified in class 435, subclasses 6, 7.1.
8. Claims 64-71, as specifically drawn to a method for diagnosing progression of hypoxia in an individual comprising measuring RTP/DRG1, PAI-1, and uPAR classified in class 435, subclasses 6, 7.1.
9. Claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring RTP/DRG1 and PAI-1, classified in class 424, subclass 9.1.

Art Unit: 1642

10. Claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring RTP/DRG1 and uPAR, classified in class 424, subclass 9.1.
11. Claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring PAI-1 and uPAR, classified in class 424, subclass 9.1.
12. Claims 72-80, as specifically drawn to a method for diagnosing preeclampsia in a pregnant woman comprising measuring RTP/DRG1, PAI-1, and uPAR classified in class 424, subclass 9.1.
13. Claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring RTP/DRG1 and PAI-1, classified in class 436, subclass 64.
14. Claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring RTP/DRG1 and uPAR, classified in class 436, subclass 64.
15. Claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring PAI-1 and uPAR, classified in class 436, subclass 64.

16. Claims 81-89, as specifically drawn to a method for assessing risk of metastasis comprising measuring RTP/DRG1, PAI-1, and uPAR classified in class 436, subclass 64.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-16 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Further, the inventions of Groups 1-16, inclusive of measuring at least two gene products, necessarily encompasses the analysis of four distinct and different combinations of gene products (*i.e.* RTP/Drg1 and PAI-1 or RTP/Drg1 and uPAR or PAI-1 and uPAR or RTP/Drg1, PAI-1, and uPAR) each of which are unique and nonobvious. The analysis of at least two genes as part of each combination represents a separate and distinct invention that would require different searches and considerations in the literature. Furthermore, Groups 1-4, 5-8, 9-12, and 13-16, although related to each other by specific gene combinations, differ by method steps and or objectives and criteria for success. For example, Groups 1-4, drawn to a method of diagnosing hypoxia in an individual, comprise distinctly different steps from the methods of Groups 5-8, drawn to diagnosing progression of hypoxia in an individual comprising analyzing time-dependent comparisons of gene products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the

Art Unit: 1642

reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at 571-272-0871. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
January 20, 2004

